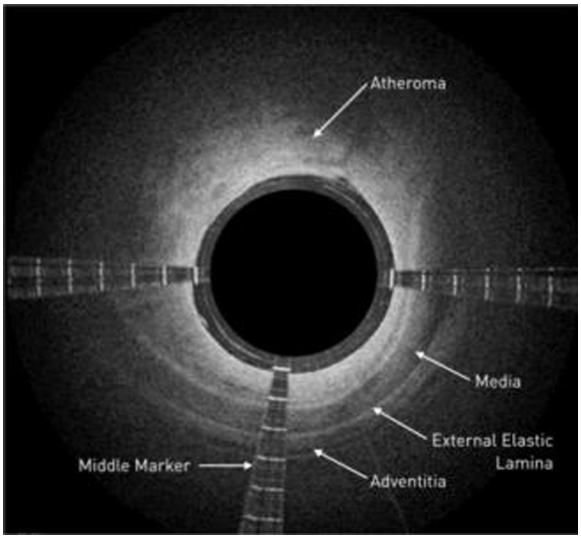

Results: 100% of CTO's in this series were crossed successfully via the true lumen without the use of assist or re-entry devices. Mean CTO crossing fluoroscopy time was 0.24 (14.4 seconds) ± 0.36 minutes using the Ocelot. Mean lesion length treated was 18.6 cm (18.63 ± 8.58 cm) (Table 1). The treated lesions represented a spectrum of calcification (mild/none=2; moderate=8; severe=6).
Conclusions: The Ocelot catheter successfully crosses peripheral arterial chronic total occlusions while eliminating, or significantly reducing fluoroscopic exposure and associated contrast administration.

TCT-539

Intraluminal Versus Re-entry Device Assisted Subintimal Revascularization of the Superficial Femoral Artery Chronic Total Occlusion: Does It Affect Patency?

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Background: Chronic total occlusions (CTO) of the superficial femoral artery (SFA) are a challenging subset of lesions encountered in peripheral interventions. CTO's of the SFA are commonly crossed either with an intraluminal (IL) or re-entry device assisted subintimal (SI) approach followed by stenting. Even though both these techniques have a high immediate procedural success rate the long term outcomes of each approach are not well studied.
Methods: We studied 215 patients (pts) (254 limbs) with obstructive SFA disease treated with nitinol self-expanding stents of comparable lesion length; there were 205 (81%) limbs with CTO and 49 (19%) pts with non-CTO. We analyzed in-stent restenosis (ISR) rates as well as demographic, procedural and laboratory characteristics in 3 subgroups of pts: without CTO; with CTO crossed IL; and with CTO crossed SI.

	Non-CTO N=49	CTO IL N=155	CTO SI N=50
Age (years)	73.02±9.1	71.94 ±9.5	74.9 ±7.9
Mean stented length, mm	248.8±72.5	251.81±99.2	280.0±91.9
GFR ml/min	52.3±22.3	62.6 ± 20.5	58.6±21.9
Rutherford class 3	34(70%)	119(79%)	35(70%)
Rutheford class ≥4	15(30%)	32(21%)	15(30%)
Mean run-off score	5.1±2.5	3.9±2.8	3.9±2.9
Mean follow up period, mo	18.4±14.7	20.5±16.5	17.2±16.9
Mean duration to ISR, mo	13.3±11.8	13.0±9.2	13.3±10.4
ISR rate (%)	23(47%)	66(42%)	24(48%)

Results: Baseline and procedural characteristcis of the studied groups presented in the table. There were no significant differences in the mean time to ISR, stented lesion length, as well as other demographic, laboratory, and procedural parameters between the studied groups except mean run-off score that was higher in non-CTO group (non CTO vs. SI CTO, p=0.05; non-CTO vs. IL CTO, p=0.01). During follow up period of 19.26±16.14 months, ISR was diagnosed in: 23 (47%) of pts of non-CTO group; 66 (42%) of IL CTO; and 24 (48%)pts of SI CTO group respectively. There were no significant differences in ISR rates between the groups (non-CTO vs. IL CTO, p=0.59; non-CTO vs. SI CTO, p=0.9; IL CTO vs. SI CTO, p=0.5).
Conclusions: In patients with long SFA lesions, we observed similar SFA ISR rates between patients with and without CTO. Furthermore, in CTO group the long term vessel patency was not affected by whether CTO was crossed using intraluminal or subintimal approach.

TCT-540

Trends in Hospital Treatments for Peripheral Arterial Disease in the United States and Impact of Payer Status on Quality of Care and Outcomes, 2007-2011

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Background: Peripheral arterial disease (PAD) affects >8 million in US. Previous studies suggested that patients with Medicare, Medicaid or no insurance received poorer quality of care leading to worse outcomes in comparison to patients with private insurance.
Methods: We analyzed all hospitalized PAD patients records from 01/2007 through 12/2011 in Nationwide Inpatient Sample (NIS) database. Temporal trends of presenting diagnoses as well as vascular procedures performed (endovascular treatment, bypass surgery and amputation) were analyzed. In addition, the unadjusted and adjusted rates of adverse in-hospital outcomes (death, myocardial infarction, bleeding, vascular complications, and acute renal failure (ARF)) were examined.
Results: The frequency of endovascular treatment for claudication from 2007 to 2011 decreased by 39.4%, while the annual incidence of bypass surgery and amputation remained unchanged. Medicare (n=731,264) and Medicaid (n=72,050) patients were more likely to undergo amputation than private insurance/HMO population (n=22,896), (adjusted OR 1.13, 95%CI 1.10-1.16, p< 0.001 and OR 1.24, 95%CI 1.20-1.29, p< 0.001, respectively). Both Medicare and Medicaid patients were less likely to undergo bypass surgery (adjusted OR 0.82, 95%CI 0.81-0.84, p< 0.001 for Medicare and OR 0.87, 95%CI 0.85-0.90, p< 0.001 for Medicaid), but more likely to undergo endovascular procedures (adjusted OR 1.18, 95%CI 1.17-1.20, p< 0.001 for Medicare and OR 1.03, 95%CI 1.01-1.06, p=0.02 for Medicaid). Medicare and Medicaid status was associated with worse in-hospital outcomes (Table).

Vascular Procedure	Outcome	Payer Status	Adjusted* Odds Ratio (95% CI)	P Value
Bypass Surgery	Death	Medicare	1.40 (1.25-1.58)	<0.001
		Medicaid	0.82 (0.66-1.03)	0.94
		Self-Pay	0.96 (0.68-1.35)	0.80
Endovascular Treatment	Death	Medicare	1.40 (1.26-1.55)	<0.001
		Medicaid	1.35 (1.13-1.62)	0.001
		Self-Pay	1.31 (0.97-1.78)	0.08
Amputation	Death	Medicare	1.56 (1.39-1.74)	<0.001
		Medicaid	1.41 (1.20-1.66)	<0.001
		Self-Pay	1.11 (0.80-1.53)	0.54

Conclusions: Medicare and Medicaid patients were more likely to undergo amputation and less likely to undergo vascular bypass surgery. Medicare or Medicaid status was associated with worse in-hospital outcomes compared to private insurance/HMO status.

TCT-541

Impact of below-the-knee intervention on the patency of superficial femoral artery lesion after concomitant angioplasty

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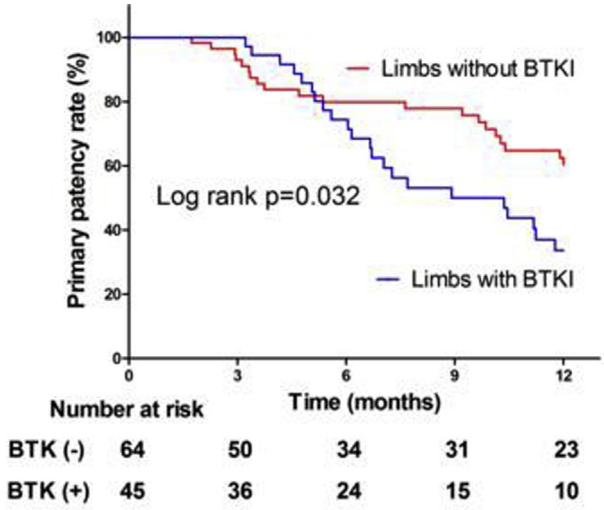
Background: Recent studies have reported presence of poor run-off vessels was related to lower patency rates of SFA lesions, however it is still uncertain the role of below-the-knee intervention (BTKI) for patency of SFA. The aim of this study was to evaluate the impact of BTKI on the patency of SFA lesions after concomitant treatment.
Methods: Percutaneous angioplasty with primary stenting at SFA was performed in 110 limbs (65 with BTKI) with 0 or 1 patent run-off vessel. Loss of patency was defined that aggravated ischemic symptoms with deterioration of calf-brachial index by ≥0.15 from the maximum postprocedural level or stenosis by duplex ultrasound,

angiography or computed tomography. We compared the outcomes of SFA angioplasty with versus without combined BTKI.
Results: More limbs treated with BTKI showed absence of any run-off vessel before angioplasty (56% vs 19%, p< 0.001). Other baseline characteristics were similar. SFA lesion length did not differ between the limbs with and without BTKI (226±101 vs 248±72 mm, p=0.214). At 1-year follow-up, overall mortality rate was 14% and 7% for patients with and without BTKI, retrospectively (p=0.235). There was no major amputation in both groups. Unexpected minor amputation rate was 11% and 3%, respectively (p=0.120). Target vessel revascularization rate for limbs with BTKI was 18% versus 11% for limbs without BTKI (p=0.292). Kaplan-Meier analysis showed limbs with BTKI have a lower 1 year patency rate (log rank p=0.032) than those without BTKI.



Conclusions: BTKI showed no beneficial impact on outcomes of SFA lesions after angioplasty in limbs with poor run-off vessels.

TCT-542

Laser Atherectomy for Treatment of Femoropoliteal In-Stent Restenosis

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Background: Femoropoliteal in-stent restenosis (FP-ISR) is associated with high rates of recurrent stenosis and stent occlusion after endovascular therapy. Laser atherectomy provides neointimal debulking and possible subsequent improved patency in the treatment of FP-ISR.
Methods: All cases of FP-ISR treated between 2006-2013 were retrospectively identified. FP-ISR was divided into three angiographic classes: Class I (≤ 50 mm length); Class II (>50 mm length); and Class III (in-stent occlusion). Baseline demographics and lesion angiographic characteristics were compared between groups. Recurrent stenosis, as assessed by duplex ultrasound, was determined routinely at 3-4 month intervals up to 24 months post-intervention.
Results: One hundred and eighteen patients underwent endovascular treatment of FP-ISR. Thirty-seven patients (31%) were treated with laser atherectomy and balloon angioplasty, while 81 patients were treated with balloon angioplasty. Patients treated with laser atherectomy had longer mean lesion length of FP-ISR (185 mm vs. 116 mm, p=0.001) and were more likely to have Class III ISR (54% vs. 20%, p=0.001) and TASC C/D lesions (64% vs. 35%, p=0.007). Procedural success was achieved in 100% of laser-assisted cases and 98% of non-laser-assisted cases. Complication rates were low, with four distal embolizations in the laser group and one in the non-laser group (p=0.01). There was no association between laser atherectomy and rates of recurrent stenosis or occlusion for patients with Class I or Class II FP-ISR. In comparison, patients with Class III FP-ISR treated with laser atherectomy were less likely to develop recurrent stenosis at one year (54% vs. 91%, p=0.05) and two year (69% vs. 100%, p=0.05) follow-up.

Variable	Laser (N = 37)	No Laser (N = 81)	P value
Age, years	73 ± 11	69 ± 11	0.06
Male (%)	18 (49)	41 (51)	0.9
ABI	0.70 ± 0.22	0.65 ± 0.18	0.3
TBI	0.33 ± 0.21	0.37 ± 0.18	0.4
Total lesion length, mm	185 ± 118	114 ± 106	0.001
Reference vessel diameter, mm	5.3 ± 0.6	5.3 ± 0.7	0.9
TASC II C/D	21 (64)	25 (35)	0.007
Tosaka Class			0.001
1	5 (14)	32 (40)	
2	12 (32)	32 (40)	
3	20 (54)	17 (20)	

Conclusions: Laser atherectomy with adjunctive balloon angioplasty may be associated with improved patency when used to treat complex FP-ISR, including longer lesions and in-stent occlusions.

TCT-543

Middle-Term Clinical Outcome of Femoropopliteal Stenting with Drug-Eluting Stent for Diabetic Patients

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Background: Previous studies revealed that diabetes mellitus is associated with the early restenosis after nitinol stenting in the femoropopliteal (FP) disease. The purpose of this study is to investigate the advantage of endovascular therapy (EVT) with drug eluting stents (DES) for FP lesions in diabetic patients.
Methods: This is a single center, retrospective observational study. Between July 2008 and April 2013, 101 FP lesions in 76 diabetic patients were treated with bare metal stents (BMS group). 52 FP lesions in 42 diabetic patients were treated with Zilver PTX paclitaxel-eluting nitinol stents (DES group). We evaluate the clinical outcomes at 8 months after EVT. Stent patency was assessed by either duplex ultrasound or angiography.
Results: Follow-up rate at 8 months were 96% (73 patients) in BMS group and 93% (39 patients) in DES group. Primary patency rates at 8 months were 92.9% with BMS and 89.6% with DES . (p=0.50) Major adverse limb events (MALE) occurred in 3 limbs with BMS and 4 limbs with DES in 8 months after stenting. (p=0.14) Survival rate at 8 months were similar. (95.9% vs 89.4% p=0.21) Event-free survival rate (freedom from all death, MALE and restenosis) were not significant different. (87.7% vs 76.9% p=0.15).
Conclusions: FP stenting for diabetic patients with DES offers no significant advantage over BMS in middle- term clinical outcome.

TCT-544

Post-Procedural Intravascular Ultrasound Findings on Short-Term Outcomes of Drug-Eluting Stent Implantation for Femoropopliteal Lesions

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Background: It has not been reported that intravascular ultrasound (IVUS) findings correlate with drug eluting stent (DES) restenosis after endovascular therapy for femoropopliteal lesions. So we investigated that in this study.
Methods: This was a single center non-randomized retrospective study. From April 2012 to March 2013, a total of 71 consecutive de novo femoropopliteal lesions in patients who underwent intravascular ultrasound (IVUS) after DES implantation were included. The mean follow-up period was 12±4 months. In-stent restenosis (ISR) was defined as a peak systolic velocity ratio >2.4 on duplex ultrasonography or >75% stenosis on angiography. ISR were detected in 14 lesions (19.7%). Subjects were classified into two groups: the patients with ISR (ISR group, 14 lesions, 12 patients) and without ISR (non-ISR group, 57 lesions, 49 patients). We compared post-procedural IVUS findings between two groups.
Results: For baseline patients and lesion characteristics, the percentage of women was higher in ISR group than non-ISR group (83.3% vs. 20.4%, p< 0.05). There were no significant differences between two groups in diabetes mellitus (33.3% vs. 32.7%, p=0.96), hemodialysis (8.3% vs. 26.5%, p=0.18), TASC II classified C or D lesions (28.6% vs. 35.1%, p=0.64), and critical limb ischemia (33.3% vs. 53.0%, p=0.22).